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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/560,288	04/27/2000	Edward Nathaniel Hanley JR.	8151-24A	3083

826 7590 12/17/2002

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EXAMINER

HAYES, ROBERT CLINTON

ART UNIT PAPER NUMBER

1647

DATE MAILED: 12/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action SummaryApplication No.
09/560,288Applicant(s)
Hanley et alExaminer
Robert C. Hayes, Ph.D.Art Unit
1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 29, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-38 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/29/02 has been entered.
2. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1647.
3. Applicant's arguments filed 1/29/02 have been fully considered but they are not deemed to be persuasive.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. The listing of references in a response (i.e, Paper Nos: 5 & 15) is not a proper information disclosure statement, if so intended. 37 CFR 1.98(b) requires a list of all patents, publications, or

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other information submitted for consideration by the Office, and must be submitted in a separate paper. Therefore, unless the references have been cited by the examiner on form PTO-892 or submitted on a PTO Form 1449, they have not been considered.

6. Claims 35-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a therapeutic composition comprising 'early childhood' human annulus and/or nucleus intervertebral disc cells (if proper antecedent basis can be shown) and a carrier that contains any specifically defined and required cell stimulants/growth factors, does not reasonably provide enablement for such cells from adolescents or adults wherein annulus and/or nucleus cells no longer exist, or for compositions missing required/defined components. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for the reasons made of record in Paper Nos: 3 & 7, and as follows.

In summary, pages 1-3 & 5 of the specification describe that cultured annulus and/or nucleus intervertebral disc cells re-express Type II collagen extracellular matrix protein and proliferate, as also argued on page 3 of the response. However, page 4 of the specification states that "[i]t is important that the cells implanted into the patient be grown from the patients own cells". In contrast, page 3 of the response states that "[t]he nucleus disappears in early childhood and becomes fibrocartilaginous in adolescents and adults", while "[t]he annulus becomes avascular in adults". However, in contrast to that asserted on page 3 of the response, no where

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on page 5 of the specification is it stated that "it would not matter if there were a few cells from the nucleus region of the disc." Moreover, in that "annulus cells of the sand rat" are not human cells, as claimed, and one can not readily extrapolate from such studies to human "therapeutic compositions", based on the teachings of Aigner et al. (1997), Guilak et al. (1999), Frick et al. (1994) and Luk et al (1997) previously made of record, one of ordinary skill in the art would not reasonably expect to isolate such cells, as currently recited, from anyone except young children based on Applicants' arguments, nor be able to make such "therapeutic compositions"; especially when any required cell stimulants/growth factors required for proliferation, etc., in order to make such cells "therapeutic", are not recited. Finally, note that no where in claim 37 is there a requirement that "the therapeutic compositions are secreting collagen"; only that a composition may contain collagen, etc., in which no other claims require such a limitation. Therefore, Applicants' arguments remain not persuasive for the reasons made of record.

7. Claims 35-38 are re-instated as rejected under 35 U.S.C. 102(a) as being anticipated by Gruber et al. (1997; IDS Ref #26), by Gruber et al. (Matrix Biology 16: 285-288 (1997)), or by Chelberg et al (J. Anat. 186: 43-53 (1995)), for the reasons made of record in Paper No: 3 and as follows.

Note that new claims 35 & 37-38 again recite similar language as in original claims 10, 11, 13-15 & 17, in which all three references teach isolated human annulus and/or nucleus intervertebral disc cells. However, in that alginate and agarose broadly met the limitations of a

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hydrogel (i.e., water containing gel), claim 36 is also anticipated. Again, note that intended uses carry no patentable weight, in that they do not materially affect the properties of the human intervertebral disc cell product composition. The issue then becomes that if the product in a product-by-process claim (i.e., a composition comprising a carrier and *in vitro* human intervertebral cells) is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983).

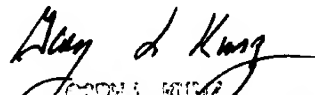
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.
May 16, 2002



GARY L. KUNZ
SENIOR PATENT EXAMINER
TECHNOLOGY CENTER 1600